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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,485

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EXAMINER

RODRIGUEZ-GARCIA, VALERIE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

07/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,485	Applicant(s) HIRANO ET AL.	
	Examiner VALERIE RODRIGUEZ-GARCIA	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 07/09/2009, 05/18/2009, 05/07/2009, 04/21/2008, 08/24/2007 and 05/23/2007.

Amendments to the claims were received on 05/18/2009. Claims 1-11 are currently pending.

This application is a 371 of PCT/JP2005/010184 filed on June 2, 2005 which claims foreign priority benefit of applications JP 2004-166486, filed on June 6, 2004, and JP 2005-099815, filed on March 30, 2005. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant's election **with traverse** of species compound

in page 68 of the specification as Ex No. 2-37, in the reply filed on 05/18/2009 is acknowledged. The traversal is on the grounds that the special technical feature of the present invention is the pharmaceutical utility of the compounds (GnRH receptor antagonism) and that the reference cited by the Examiner does not describe a utility. Applicant's argument is unpersuasive because the claims are drawn to chemical compounds. It is apparent that these compounds share a special technical feature, which is the core structure, as explained in the requirement for species election of 03/18/2009. Since the core has been previously disclosed, there is lack of a special

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technical feature (see requirement of 03/18/2009). Therefore, the requirement is deemed proper and is therefore **maintained**.

The claims have been examined according to M.P.E.P. § 803.02. The elected species compound Ex No. 2-37 is free of the art. The search has been expanded to include all the claims and limitations.

Pursuant to Applicant's response, claims 1-11 are treated on the merits in this action. This is the first Office Action on the merits of the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1, in line 4, recites “[symbols in the formula...]”. The brackets used in instant claim 1 are generally used in the Office to delete recitations from the claims. It is not clear if applicants want to delete the bracketed recitation. Appropriate correction is required.
4. Claims 1, 3 and 6 recite “with (aryl or heteroaryl)”. It is unclear what is meant by the parenthesis.
5. It is unclear what the proviso in claim 1 is excluding or including.
6. Claim 8 discloses at beginning of the claim, “...or a pharmaceutically acceptable salt thereof... of” and at the end of the claim “...a pharmaceutically acceptable salt

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thereof". What is pharmaceutically acceptable salt of a pharmaceutically acceptable salt?

7. Claims 5 and 8 recite " the propane-1,3-dione derivative..., which is at least one compound...". The propane-1,3-dione derivative or the salt is one compound. What is meant by "at least one compound"? Applicants are suggested to replace "at least one compound" with –a compound-.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,960,591.

Although the conflicting claims are not identical, they are not patentably distinct from

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each other because the reference claims include the instantly claimed compounds. The reference teaches a pharmaceutical composition comprising compounds of formula (I), which provides sufficient motivation to one of ordinary skill in the art to prepare the compounds of formula (I). The reference provides preparation of the compounds and the claims are drawn to a composition thereof. One of ordinary skill in the art would have been motivated to prepare the compounds of formula (I) as these compounds are taught to be useful as pharmaceutical agents.

9. Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,569,688.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims substantially overlap the compounds of the reference claims, see the claims in each of the application. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the compounds from the reference claims and/or use the compounds in any of the methods taught by the reference, including those instantly claimed, because the skilled artisan would have had the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

Claim Objections

10. Claim 1 is objected to for containing a (I) symbol with no formula. There are two (I) symbols in the claim. Claims 1, 4, 6 and 9 recite "by the general formula", however,

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there are formulae (I), (Ia) and (Ib), and these are not general, because all the variables are defined. Applicants are suggested to remove "general" from the recitation.

Specification Objection - Title

Applicant is reminded of the proper content of the title of the invention.

The title of the invention should be brief, but technically accurate and descriptive, preferably from two to seven words. See 37 CFR 1.72(a) and MPEP § 606.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In the revised title, the examiner suggests including the name of the main core of the chemical structure (e. g. benzimidazolidine propane-1,3-dione) and the alleged utility possessed by the compounds applicants regard as their invention.

Telephone Inquiry

Claims 1-11 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/
Primary Examiner, Art Unit 1626

/V. R.G./
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